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Premium

'Can't penalise US NGO for violating drug trial norms'

PATH conducted unethical trials for HPV vaccine on tribal girls in Andhra, Gujarat

Written by [Utkarsh Anand](#) New Delhi | Updated: April 18, 2015 02:37 IST







PATH conducted unethical trials for HPV vaccine on tribal girls in Andhra, Gujarat.

The NDA government Friday told the Supreme Court that no specific penalties could be imposed on the Bill and Melinda Gates Foundation-funded Programme for Appropriate Technology in Health (PATH) for violating norms in conducting the vaccination trials on tribal girls in Andhra Pradesh and Gujarat.

Pointing out that the current legal regime had no provision of penalties, the Ministry of Health and Family Welfare has expressed its inability to proceed against the NGO PATH despite a parliamentary panel recommending strict actions.

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The Parliamentary Committee report had in 2013 indicted government officials and the US agency for colluding to conduct unethical clinical trials for HPV vaccine against cervical cancer in Andhra Pradesh and Gujarat. It had said that the norms and procedures were overlooked by the government agencies while allowing clinical trials among adolescent girls for Human Papilloma Virus (HPV) vaccine, while asking the ministry to take action.

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The ministry subsequently sought an opinion from the Department of Legal Affairs, which replied that since the trials had been suspended and PATH was issued a “warning”, requisite actions had already been taken under the Drugs & Cosmetics Act, 1940.

“As of now, there are no specific penalties for provisions relating to clinical trials under the Act. Therefore, as per the legal provisions prevalent at the point of time under the Act and pertinent rules, ICMR has already taken action admissible under these rules,” the ministry said.

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There seems to be no movement also with respect to another recommendation by the parliamentary panel. Noting that the trials were conducted in three more countries – Uganda, Vietnam and Peru – the panel had recommended the government to take up the matter with these countries through diplomatic channels to take action accordingly. It further urged the government “to report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide.”

However, the Ministry said that the Ministry of External Affairs was requested in January 2014 to ascertain whether similar studies were conducted by PATH in other countries and whether HPV vaccine has been introduced in the national health programmes of such countries but no information has been received till date. The MEA has been requested again to adduce the information at the earliest.

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The affidavit added that MEA has also been asked to flag the issue with the US government so that actions could be taken against PATH if it has breached regulations there.

The response has come to a PIL filed by Kalpana Mehta and some other health activists. It alleges that the vaccines – Gardasil and Cervarix – are unproven and hazardous HPV vaccines being marketed in India by MSD Pharmaceuticals Pvt Ltd and GlaxoSmithKline Ltd.

The two vaccines were introduced in India in 2007 and till 2010, around 24,000 girls Gujarat and Andhra Pradesh were vaccinated. The PIL claimed seven girls succumbed during the vaccine trial, a claim denied by the enquiry committee set up by the government.

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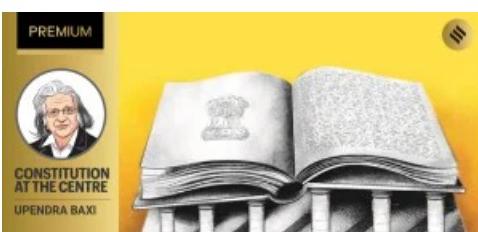
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